

Federal Register containing information proposing that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

(A) is GRASE and is not misbranded if marketed in accordance with such order;

(B) is not GRASE and is misbranded; or

(C) is not GRASE and is misbranded because the data are insufficient to classify such ingredient or combination of ingredients as GRASE and not misbranded and additional information is necessary to allow the Secretary to determine otherwise;

(8) the term “sponsor” means the person that submitted—

(A) a request under section 360fff-1 of this title;

(B) a pending request; or

(C) any other application subject to this part;

(9) the term “sunscreen” means a drug containing one or more sunscreen active ingredients; and

(10) the term “sunscreen active ingredient” means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation.

(June 25, 1938, ch. 675, §586, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2035.)

CONSTRUCTION

Pub. L. 113-195, §2(b), Nov. 26, 2014, 128 Stat. 2045, provided that: “Nothing in the amendment made by this section [enacting this section and sections 360fff-1 to 360fff-5 of this title] shall be construed to—

“(1) limit the right of a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360fff(8)], as added by subsection (a) to request that the Secretary of Health and Human Services convene an advisory committee; or

“(2) limit the authority of the Secretary of Health and Human Services to meet with a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)).”

§ 360fff-1. Submission of requests

Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof (including dosage form, dosage strength, and route of administration) is GRASE and should be included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen.

(June 25, 1938, ch. 675, §586A, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2036.)

§ 360fff-2. Eligibility determinations; data submission; filing

(a) Eligibility determinations

(1) In general

Not later than 60 calendar days after the date of receipt of a request under section 360fff-1 of this title, the Secretary shall—

(A) determine, in accordance with paragraph (2), whether the request is eligible for further review under subsection (b) and section 360fff-3 of this title;

(B) notify the sponsor of the determination of the Secretary; and

(C) make such determination publicly available in accordance with paragraph (3) and subsection (b)(1).

(2) Criteria for eligibility

(A) In general

To be eligible for review under subsection (b) and section 360fff-3 of this title, a request shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, that—

(i) is not included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen; and

(ii) has been used to a material extent and for a material time under such conditions, as described in section 321(p)(2) of this title.

(B) Establishment of time and extent

A sponsor shall include in a request under section 360fff-1 of this title the information required under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) to meet the standard described in subparagraph (A)(i).

(3) Public availability

(A) Redactions for confidential information

If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined under paragraph (1)(A) to be eligible for further review, the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 331(j) of this title.

(B) Identification of confidential information by sponsor

At the time that a request is made under section 360fff-1 of this title, the sponsor of such request shall identify any information that such sponsor considers to be confidential information described in subparagraph (A).

(C) Confidentiality during eligibility review

The information contained in a request under section 360fff-1 of this title shall remain confidential during the Secretary’s consideration under this section of whether the request is eligible for further review consistent with section 330.14 of title 21, Code of Federal Regulations (or any successor regulations).

(b) Data submission and filing of requests

(1) In general

In the case of a request under section 360fff-1 of this title that is determined to be eligible

under subsection (a) for further review under this section and section 360fff-3 of this title, the Secretary shall, in notifying the public under subsection (a)(1)(C) of such eligibility determination, post the eligibility determination on the Internet website of the Food and Drug Administration, invite the sponsor of such request and any other interested party to submit comments, and provide a period of not less than 45 calendar days for comments in support of or otherwise relating to a GRASE determination, including published and unpublished data and other information related to the safety and efficacy of such request.

(2) Filing determination

Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, the Secretary shall determine whether the data and other information submitted by the sponsor under this section are sufficiently complete, including being formatted in a manner that enables the Secretary to determine the completeness of such data and information, to enable the Secretary to conduct a substantive review under section 360fff-3 of this title with respect to such request. Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, if the Secretary determines—

(A) that such data and other information are sufficiently complete, the Secretary shall—

(i) issue a written notification to the sponsor of the determination to file such request, and make such notification publicly available; and

(ii) file such request made under section 360fff-1 of this title; or

(B) that such data and other information are not sufficiently complete, the Secretary shall issue a written notification to the sponsor of the determination to refuse to file the request, which shall include the reasons for the refusal, including why such data and other information are not sufficiently complete, and make such notification publicly available.

(3) Refusal to file a request

(A) Request for meetings; submission of additional data or other information

If the Secretary refuses to file a request made under section 360fff-1 of this title, the sponsor may—

(i) within 30 calendar days of receipt of written notification of such refusal, request, in writing, a meeting with the Secretary regarding the filing determination; and

(ii) submit additional data or other information.

(B) Meetings

(i) In general

If a sponsor seeks a meeting under subparagraph (A)(i), the Secretary shall convene the meeting within 30 calendar days of the request for such meeting.

(ii) Actions after meeting

Following any meeting held under clause (i)—

(I) the Secretary may file the request within 60 calendar days;

(II) the sponsor may submit additional data or other information; or

(III) if the sponsor elects, within 120 calendar days, to have the Secretary file the request (with or without amendments to correct any purported deficiencies to the request)—

(aa) the Secretary shall file the request over protest, not later than 30 calendar days after the sponsor makes such election;

(bb) at the time of filing, the Secretary shall provide written notification of such filing to the sponsor; and

(cc) the Secretary shall make such notification publicly available.

(iii) Requests filed over protest

The Secretary shall not require the sponsor to resubmit a copy of the request for purposes of filing a request filed over protest, as described in clause (ii)(III).

(C) Submissions of additional data or other information

Within 60 calendar days of any submission of additional data or other information under subparagraph (A)(ii) or (B)(ii)(II), the Secretary shall reconsider the previous determination made under paragraph (2) with respect to the applicable request and make a new determination in accordance with paragraph (2).

(4) Public availability

(A) Redactions for confidential information

After the period of confidentiality described in subsection (a)(3)(C), the Secretary shall make data and other information submitted in connection with a request under section 360fff-1 of this title publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 331(j) of this title.

(B) Identification of confidential information by sponsor

A person submitting information under this section shall identify at the time of such submission the portions of such information that the person considers to be confidential information described in subparagraph (A).

(June 25, 1938, ch. 675, §586B, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2036.)

§ 360fff-3. GRASE determination

(a) Review of new request

(1) Proposed sunscreen order

In the case of a request under section 360fff-1 of this title, not later than 300 calendar days after the date on which such request is filed under subsection (b)(2)(A) or (b)(3)(B)(ii)(III) of section 360fff-2 of this title, the Secretary—